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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,796	12/04/2001	Eija Pirhonen	01942-00007	9843

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EXAMINER

YOUNG, MICAH PAUL

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 09/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/006,796	<b>Applicant(s)</b> PIRHONEN ET AL.	
	<b>Examiner</b> Micah-Paul Young	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

**Acknowledgment of Papers Received:** Amendment/Response dated 9/24/04.

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over the disclosures of Dunn et al (WO 91/01126 hereafter '126).

4. Dunn et al discloses biodegradable system for regenerating the periodontium. The implant comprises a polymeric matrix along with various other solvents and components. The polymers are selected from polylactides, polyglcolides, and polyamides (pg. 8, lin. 23 – 38). N-methyl-2-pyrrolidone is recited as a solvent in the system (pg. 9, lin. 23 – 25). Once implanted/injected into the body the solvents dissipate leaving a more rigid polymer comprising a porous polymer with bioactive agents such as growth hormones and/or antimicrobial agents lodged within the polymeric matrix (pg. 11, lin. 13 – pg. 12, lin. 8). Since claims 1-8 are drawn to a product is irrelevant the order in which the product is made. Claims 6 and 7 are deemed product-by-process claims and do not impart patentability on the invention.

5. As discussed above Dunn et al discloses many of the essential elements of the invention. Dunn discloses a biodegradable implant used for rebuilding tissue, where the

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implant comprises N-methyl-2-pyrrolidone, which dissipates from the implant upon placement in the body. What is lacking however is an explicit disclosure to the differing order of manufacture recited by applicant. It is the position of the examiner that these claims are non critical to the patentability of the invention. Dunn presents an identical product made with identical components, used for the same purpose of regenerating tissue. The Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

6. It would be within the level of skill in the art to manipulate the order of the procedure, in order to determine the most effective manufacturing method. This can be accomplished through routine experimentation in the art. With this in mind, it would have been obvious to one of ordinary skill in the art to follow the teachings and suggestions of Dunn in order to rebuild periodontal tissue after surgery. A skilled artisan would have expected to attain a porous, biodegradable implant useful in rebuilding periodontal tissue after dental surgery. The bioactive agents in the implant would help treat any possible infections, during the healing process.

***Response to Arguments***

7. Applicant's arguments filed 9/29/04 have been fully considered but they are not persuasive. Applicant argues elements, which do not impart patentability on the claims.

8. Applicant argues that since the implant of the instant claims is solid before entering the body it is distinct over the prior art, which is a liquid before implantation. However it is the position of the Examiner that this limitation is drawn to process step and renders the product claims product-by-process claims, which would not distinguish them over identical products of the prior art. Further applicant has yet to provide a patentable distinction other than the prior body form of the implant. The claims are drawn to the implant in the body, and in that respect the implant of Dunn is identical to that of the instant claims. The Dunn reference teaches identical polymers and identical plasticizers used to create a product within the same field of biodegradable periodontal implants. Burden is shifted to applicant to provide a patentable distinction between the claims of the instant invention and the teachings of the Dunn reference. Until such evidence of unexpected results and patentable distinction is presented the claims remain obviated by the art.

***Conclusion***

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Micah-Paul Young  
Examiner  
Art Unit 1618

  
MP Young

  
THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
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